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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,823	07/11/2005	Danuta Ciok	P70681US0	6121
136 7590 09/11/2007 JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004			EXAMINER HAND, MELANIE JO	
			ART UNIT 3761	PAPER NUMBER
			MAIL DATE 09/11/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/541,823

Applicant(s)

CIOK ET AL.

Examiner

Melanie J. Hand

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3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 37-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Arguments*

Applicant's arguments with respect to claims 1-36 are moot in view of the cancellation of those claims by applicant.

Applicant argues with respect to claim 37 and 48 that the flange 8, 16 does not aid in locking the torus in the rolled up position. While this is true, Nielsen does teach a first adhesive surface as claimed of wafer 2 that, together with adhesive mass 7, locks the torus 20 in the rolled-up position in the manner shown in Figs. 1 and 7. The adhesives claimed and those used in the device of Nielsen are substantially identical thus the adhesives taught by Nielsen lock the torus in said rolled up position as claimed. As to applicant's argument that Nielsen does not teach a second hydrophobic adhesive, applicant is referred to Page 8, lines 4-13 wherein Nielsen teaches moldable adhesive mass 7 that serves as the second adhesive surface as claimed.

As to applicant's arguments regarding inconsistencies in the Office action regarding the first adhesive surface, this inconsistency has been corrected in the rejections herein. Nielsen teaches a wafer 2 with adhesive applied to the skin-facing surface, thus a first adhesive surface as claimed. As to applicant's argument regarding the Office's statement that wafer 2 is integral with sealing member 5. This too has been corrected by referring to Nielsen's teaching that the first adhesive surface is the surface of wafer 2 facing the user's skin to which adhesive has been applied. As to applicant's argument that Nielsen does not teach that the first adhesive is compatible with the second, Nielsen teaches the same adhesives for both surfaces on Page 8, lines 8-10, thus they are compatible. Further the first and second adhesives taught by Nielsen are considered compatible in that they meet the claim limitations, and thus the limitation of

compatibility between said first and second adhesives flows inherently and necessarily from the teachings of Nielsen.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 37-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Nielsen (WO 98/53771).

With respect to **claim 37**: Nielsen teaches an ostomy appliance body side member 1 comprising an adhesive wafer 2 having an inner rim (the wafer is annular) defining a hole 3 for accommodating a stoma, a first adhesive surface for securing the appliance to the user's skin and a second surface covered with a carrier sheet 16, a portion of the adhesive wafer surrounding the stoma having balanced plastic and elastic properties. A central part of the second surface surrounding said stoma-accommodating hole 3 is provided with a hydrophobic adhesive 7 compatible with the first adhesive surface that allows the hole to be enlarged by rolling up the inner rim to form a torus 20, said torus 20 being locked in said rolled up position by adhesion between the first adhesive surface and said hydrophobic adhesive 7 as provided on said second surface. (Figs. 1,7, Page 6, lines 8-17, Page 8, lines 4-7; Page 8, line 26 – Page 9, line 5)

With respect to **claim 38**: The first adhesive surface of adhesive wafer 2 is made of a hydrogel, which is a moisture-absorbing material. (Page 8, lines 8-10)

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With respect to **claim 39**: Adhesive wafer 2 is made from an adhesive including hydrocolloids.

(Page 8, lines 8-10)

With respect to **claim 40**: As can be seen in Fig. 1, the carrier sheet 16 is absent on a central part of the second surface surrounding the stoma.

With respect to **claim 41**: The hydrophobic adhesive 7 stretches under at least a portion of the carrier sheet.

With respect to **claim 42**: A release liner 15 protects the second adhesive surface. (Fig. 1, Page 6; lines 9, 10)

With respect to **claim 43**: The carrier sheet 16 extends to the central part of the wafer. (Fig. 1)

With respect to **claim 44**: The carrier sheet 16 on a central part of the second surface of the adhesive wafer 2 surrounding the stoma is provided with a weakening pattern in the form of a slit liner in the area defining handle 17. (Page 6, lines 23-25)

With respect to **claim 45**: The part of the adhesive wafer 2 surrounding the stoma is in the form of an exchangeable sealing member 7 disposed in a hole of the wafer and having a hole for accommodating a stoma. (Fig. 1)

With respect to **claim 46**: Body side member 1 further comprises a coupling component for releasable attachment of a receiving bag 4.

With respect to **claim 47**: A body side member as claimed in claim 28, wherein the coupling means are matching coupling rings 18. (Page 8, line 22)

With respect to **claim 48**: Nielsen teaches an ostomy sealing member in the form of a mouldable mass or ring 7 having balanced plastic and elastic properties comprising a first adhesive surface to the skin and to seal around a stoma and between the stoma and an ostomy appliance 1 adapted to receive secretions from the stoma, a second surface facing away from the user and an inner rim defining a hole 3 for accommodating a stoma, said sealing arrangement configured to allow enlargement of said stoma-accommodating hole 3 by rolling up the inner rim of the hole 3 to form a torus 20 before placing the sealing member 7 around the stoma, a part of the second surface surrounding the hole 3 having a hydrophobic adhesive thereon which is compatible with the first adhesive surface to lock the torus 20 in said rolled up position even when said first adhesive surface is exposed to moisture. (Figs. 1,7, Page 6, lines 8-17, Page 8, lines 4-7; Page 8, line 26 – Page 9, line 5)

With respect to **claim 49**: Sealing member 7 is made from an adhesive including hydrocolloids. (Page 8, lines 8-10)

With respect to **claim 50**: Nielsen teaches a method of applying an ostomy appliance body side member member having an adhesive wafer 2 with an inner rim that defines a hole 3 for accommodating a stoma, a first adhesive surface for securing the appliance to a user's skin and a second surface covered with a carrier sheet 16, a portion of the adhesive wafer surrounding the stoma having balanced plastic and elastic properties, a central part of the second surface

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surrounding said stoma-accommodating hole being provided with a hydrophobic adhesive compatible with the first adhesive surface of the adhesive wafer, the method comprising a) enlarging the hole to the size of the stoma by rolling the inner rim of the hole of the sealing member forming a torus 20 (Page 12, lines 3-13), b) locking the torus 20 to the second surface of the sealing member 7 in its rolled position by contact between the hydrophobic adhesive of member 7 and the first adhesive surface (Page 12, lines 14-17), c) aligning the stoma and the stoma-accommodating hole of the ostomy appliance body side member 1 (Page 12, lines 10-13) and placing the body side member on the abdomen of the ostomate with the stoma projecting into the hole, creating a snug fit between the appliance and the ostomy. (Page 12, lines 10-13)

With respect to **claim 51**: Nielsen teaches a method of applying a separately exchangeable ostomy sealing member 2 in a body side member 1, said sealing member having balanced plastic and elastic properties and including an inner rim that defines a first hole 3 for accommodating a stoma, a first adhesive surface adapted for securing the sealing member to a user's skin and for receiving secretions from the stoma, and a second surface facing away from the user, a central part of the second surface surrounding said first hole being provided with a hydrophobic adhesive 7 compatible with the first adhesive surface of the adhesive wafer, the method comprising a) locating the stoma and aligning the stoma and the hole of the body side member and placing the body side member on the abdomen of the ostomate with the stoma projecting into the hole (Page 11, line 25 – Page 12, line 3), b) enlarging the hole of the sealing member by rolling the inner rim of the hole of the sealing member forming a torus 20 (Page 12, lines 3-6), c) adapting the hole to the size of the stoma (Page 12, lines 10-13), d) locking the torus 20 to the second surface of the sealing member 7 in its rolled position by contact between

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the adhesive surface and the second surface of the sealing member (Page 12, lines 14-17), e) aligning the stoma and the second hole of the ostomy sealing member (Page 12, lines 10-13) and f) placing the sealing member 7 in the second hole of the body side member on the abdomen of the ostomate with the stoma projecting into the first hole 3, creating a snug fit between the appliance and the ostomy. (Fig. 1, Page 12, lines 10-13)

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand  
Examiner  
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August 31, 2007

**TATYANA ZALUKAEVA**  
**SUPERVISORY PRIMARY EXAMINER**

A handwritten signature in black ink, appearing to read 'Tatyana', written over the printed name and title.